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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,832	06/26/2000	Leslie H. Kondejewski	7900-0015.30	2421

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	18

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/603,832	Kondejewski
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 24, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-9* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2003 has been entered.

Specification

2. The applicant has amended claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) over Anderson (U.S. Patent 6,242,213 B1) (June 5, 2001) in view of Yan (U.S. Patent 5,856,928) (January 5, 1999).

Anderson teaches a coiled-coil polypeptide composition (Column 6, line 65 to column 7, line 1), comprising

a template of the form (abcdefg)n (Column 6, lines 18-24), where n is at least three, a and d are amino acids each selected from the group consisting of leucine and isoleucine (Column 6, line 18 to column 7, line 1).

Anderson inherently teaches the sequence formed by the positions (bcdefg)n is a sequence of amino acids from a solvent-accessible region of an epitope from a selected protein (Column 6, lines 24-25). This rejection is based on the fact that segments of proteins containing polar amino acids are defined as solvent-accessible region. In this case, segments g and e containing oppositely charged residues will inherently provide the solvent-accessible region of an epitope from a selected protein.

Anderson teaches the composition where a is isoleucine and d is leucine (Column 6, line 65 to column 7, line 1).

Anderson teaches the composition wherein the coiled-coil polypeptide is comprised of two polypeptide chains arranged in a parallel configuration (Column 6, lines 14-29 and Column 6, line 65 to column 7, line 1).

Anderson teaches the composition wherein n is seven which is in between about 3 to about 20 (Column 6, lines 18-24).

Anderson does not teach the composition, wherein the solvent-accessible region is not in a coiled-coil conformation in its native state.

Yan teaches the composition (prion protein in this case), wherein the solvent-accessible region is not in a coiled-coil conformation in its native state (Column 40, lines 47-59).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the composition (prion protein in this case), wherein the solvent-accessible region is not in a coiled-coil conformation in its native state of Yan in the polypeptide composition of Anderson, since Yan states, "The gelling proteins- fibrinogen, beta amyloid, and prions- are either wound-healing or disease-causing agents (Column 40, lines 58-59)." An ordinary practitioner would have been motivated to substitute and combine the composition (prion protein in this case), wherein the solvent-accessible region is not in a coiled-coil conformation in its native state of Yan in the polypeptide composition of Anderson in order to achieve the express advantages, as noted by Yan, of an invention that can detect gelling

proteins- fibrinogen, beta amyloid, and prions- which are either wound-healing or disease-causing agents.

5. Claims 6-9 are rejected under 35 U.S.C. 103 (a) over Anderson (U.S. Patent 6,242,213 B1) (June 5, 2001) in view of Yan (U.S. Patent 5,856,928) (January 5, 1999) further in view of Prusiner et al. (U.S. Patent 5,792,901) (August 11, 1998).

Anderson in view of Yan teach the polypeptide composition of claims 1-5 as described above including the alpha-helical surface regions of cellular proteins (Column 6, lines 18-40).

Anderson in view of Yan do not teach the epitopes are exposed surface regions of infectious prion protein.

Prusiner et al. teach the epitopes are exposed surface regions of infectious prion protein (Abstract and Example 4).

Anderson in view of Yan do not teach the cellular prion protein is from hamster or human.

Prusiner et al. teaches the cellular prion protein is from human (Abstract and Example 4).

Anderson in view of Yan do not teach the epitope having SEQ ID NO:5.

Prusiner et al. teach the epitope having SEQ ID NO:5 (Figure 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the epitopes present on the exposed surface regions of infectious prion protein consisting of SEQ ID NO:5 of Prusiner et al. in the polypeptide composition of Anderson in view of Yan, since Prusiner et al. state, "Yet another object of the invention is to provide for a method of testing samples for the presence of prions."

(Column 6, lines 17-18). An ordinary practitioner would have been motivated to substitute and combine the epitopes present on the exposed surface regions of infectious prion protein of Prusiner et al. in the polypeptide composition of Anderson in view of Yan, in order to achieve the express advantages, as noted by Prusiner et al., of an invention that provides for a method of testing samples for the presence of prions.

Response to Amendment

6. In response to amendment, previous 103 (a) rejections have been maintained properly.

Response to Arguments

7. Applicant's arguments filed on January 24, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., changing any protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that applicant's motivation is different from Yan reference (U.S. Patent 5,856,928), the fact that applicant has recognized another advantage (changing any protein region that is not in a coiled-coil conformation in its native state into a coiled-coil polypeptide using a coiled-coil template) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant then argues the 103 rejection is improper because it is "obvious to try" and lacks a reasonable expectation of success.

With regard to the "obvious to try" argument, The MPEP 2143.02 states "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no

reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Yan reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different proteins like fibrinogen, beta-amyloid and prions were actually experimentally studied and found to be functional as wound-healing or disease causing agents (Column 40, lines 47-59). This evidence of functionality trumps the attorney arguments, which argues that Yan reference is an invitation to research, since Yan steps beyond research and shows the functional product.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634

February 4, 2003

ARUN K. CHAKRABARTI
PATENT EXAMINER